



## Frequently Asked Questions

### ***What is Barrett's esophagus?***

Barrett's esophagus is a precancerous condition affecting the lining of the esophagus, the muscular tube that carries food, liquids and saliva from the mouth to the stomach. Normally, the esophagus is lined by a layer of short, squat cells, called squamous cells. This lining is similar to skin in that it is multilayered and protects the underlying esophagus from injury resulting from swallowed food and reflux of gastric contents. When chronic gastric reflux occurs and exposes the lining of the esophagus to acid, this lining can be injured and break down.

### ***What causes Barrett's esophagus?***

Barrett's esophagus results from chronic exposure of the esophagus to the gastric contents of the stomach caused by gastroesophageal reflux disease, commonly known as GERD. With prolonged acid exposure, normal cells can undergo a genetic change and transform into taller columnar cells. These Barrett's cells are vulnerable to further changes that can lead to cancer.

### ***Who is at risk for developing Barrett's esophagus?***

Approximately 44% of U.S. adults experience symptoms of GERD almost monthly while 18% experience symptoms weekly.<sup>1</sup> A result of prolonged GERD, Barrett's esophagus occurs in approximately 13% of Caucasian men over the age of 50.<sup>2</sup>

### ***How many people have Barrett's esophagus?***

In a study published in 2005, Barrett's esophagus was estimated to affect approximately 3.3 million adults in the United States.<sup>3</sup>

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<sup>1</sup> Shaheen N, Ransohoff DF. Gastroesophageal reflux, Barrett's esophagus and esophageal cancer. *Journal of the American Medical Association*. 2002; 287: 1972-1981.

<sup>2</sup> Westhoff B, Brotze S, Weston A, et al. The frequency of Barrett's esophagus in high-risk patients with chronic gerd. *Gastrointestinal Endosc*. 2005; 61:226-231.

<sup>3</sup> "Study provides first estimate of U.S. population affected by Barrett's esophagus". [Gastro.org](http://www.gastro.org). 2006. American Gastroenterological Association. <[www.gastro.org/wmspage.cfm?parm1=1834](http://www.gastro.org/wmspage.cfm?parm1=1834)> Accessed June, 2006



### ***How is Barrett's esophagus diagnosed?***

A physician may evaluate a patient for Barrett's esophagus if the patient has severe or prolonged GERD symptoms. Even if a patient's heartburn or GERD symptoms disappear, the patient could still have Barrett's esophagus or worse, the condition could have progressed to more advanced stages of the disease. To diagnose Barrett's a physician performs an endoscopy, a procedure that allows inspection and tissue sampling of the esophagus.

### ***Are more proactive treatment options available?***

Yes. Ablation, which involves removing or destroying tissue inside the body, has been used to treat Barrett's esophagus for more than fifteen years. However, ablation therapy is not widely used to treat Barrett's due to limitations associated with existing technology. BARRX Medical, Inc. has developed new tools for the treatment of Barrett's esophagus that addresses the limitations of existing technology, making broad use of endoscopic ablation of the esophagus practical. The HALO<sup>360</sup> and HALO<sup>90</sup> Systems provide uniform and controlled ablative therapy at a consistent depth, which can remove Barrett's cells and allow the regrowth of normal cells. They also provide preset treatment parameters and fixed energy capabilities, making it possible for physicians to effectively treat patients without injuring healthy underlying tissue. The ability to provide a controlled amount of ablative therapy to diseased tissue significantly reduces the risk of complications normally associated with other forms of ablation therapy. For the first time, the HALO<sup>360</sup> and HALO<sup>90</sup> Systems offer a proactive approach to Barrett's esophagus.

### ***How does the HALO<sup>360</sup> System work?***

Initially, a HALO<sup>360</sup> Sizing Balloon is used to size the esophagus. A correctly sized ablation catheter is then inflated within the area of the Barrett's. The HALO<sup>360</sup> Energy Generator is activated to deliver a rapid (less than one second) burst of ablative energy which removes a very thin (less than one millimeter) layer of the diseased esophagus. This ablation (removal of tissue) is tightly controlled so as to avoid any injury to the normal, healthy underlying tissues.<sup>4</sup> New healthy tissue replaces the ablated Barrett's tissue in three to four weeks for most patients, according to trial results. The procedure is performed without incisions using conscious sedation in an out-patient setting. In clinical studies, the median procedure time was 26 minutes. Minor discomfort, which may be experienced by some patients, can be well-managed with medication. Following ablation therapy, patients resume acid suppression therapy.

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<sup>4</sup> Ganz RA, Utley DS, Stern RA, et al. Complete ablation of esophageal epithelium with a balloon-based bipolar electrode: a phased evaluation in the porcine and in the human esophagus. *Gastrointest Endosc* 2004; 60:1002-10.

### ***How does the HALO<sup>90</sup> System work?***

Using standard endoscopic skills, the physician directs the ablation catheter to the diseased area of the esophagus. The HALO energy generator is then activated to deliver a short burst of ablative energy, which removes a very thin layer of the diseased esophagus. The procedure, which in clinical studies had a median procedure time of 15 minutes, is performed without incisions using conscious sedation in an out-patient setting.

### ***What happens if Barrett's esophagus goes untreated?***

Untreated Barrett's esophagus can advance from its earliest stage of intestinal metaplasia to low or high-grade dysplasia, and result in the development of a type of esophageal cancer called adenocarcinoma.<sup>5</sup> Patients with intestinal metaplasia have a combined risk of 1.4% per year of progressing to high-grade dysplasia or cancer, which may result in an esophagectomy procedure.<sup>6</sup> The majority of patients who develop an advanced esophageal cancer are unaware that they have Barrett's esophagus.

### ***How is Barrett's esophagus treated today?***

Patients diagnosed with Barrett's esophagus are treated for GERD symptoms and advised to return at scheduled intervals ranging from every three months to every three years for a repeat endoscopy and tissue inspection. This "watch and wait" approach is called surveillance. The objective of surveillance is to monitor the progression of the disease. However, surveillance can be burdensome for the patient in many ways. First, an endoscopy requires a visit to the hospital, anesthesia and multiple tissue samples (biopsies) extracted from the patient's esophagus. Patients typically need a few days to recover. This recovery period usually includes a modified diet of liquid or soft foods.

### ***Who should be considered for the ablation procedure?***

Under a physician's direction this procedure could be used to treat any patient with Barrett's esophagus. Patients have been successfully treated and cured of both non-dysplastic and dysplastic Barrett's esophagus. The HALO<sup>360</sup> system used in the clinical trials was cleared by the U.S. Food and Drug Administration in 2001 and has been commercially available since January 2005. HALO<sup>90</sup> system was cleared by the FDA in 2006 and became commercially available in the U.S. in January 2007. Studies have shown that almost all patients can be completely cleared of their Barrett's with a diligent regiment of HALO ablation treatments.

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<sup>5</sup> Reid B.J and Weinstein W. M. Barrett's esophagus and adenocarcinoma. *Gastroenterology Clinics of North America* 1987; 38: 477-492.

<sup>6</sup> Sharma P, Falk GW, Weston AP, et al. Dysplasia and cancer in a large multicenter cohort of patients with Barrett's esophagus. *Clin Gastroenterol Hepatol* 2006; 4:566-572.

***What are the potential benefits of the HALO Systems?***

The HALO Systems remove abnormal cells from the surface of the esophagus, without causing injury to the normal, healthy underlying tissues. To date, the systems have been safely evaluated in more than 35,000 patients. In clinical studies, greater than 98.4 percent of participants were Barrett's-free after one to two treatment sessions (at 30 month follow up). Among those with residual Barrett's cells, greater than 90 percent of the diseased cells were gone. Clinical studies show that when the abnormal cells of the Barrett's esophageal tissue are removed they are replaced by normal, healthy tissue within three to four weeks. Some patients in clinical studies have demonstrated to be Barrett's free for over five years.

***How can patients and physicians find out more about the ablation procedure?***

Patients and physicians can learn about the procedure by visiting the company Web site at [www.barrx.com](http://www.barrx.com) or by calling 1-888-662-2779 (1-888-66-BARRX).

***What is the cost of the procedure?***

In the U.S., most procedures are reimbursed for the endoscopic ablation procedure. Patients should check with their individual physician, hospital or insurance provider regarding their individual coverage.

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